

Application No. 10/055,504  
Filed: October 25, 2001

### **REMARKS**

The claim amendments and remarks herein are responsive to the Final Office Action dated September 7, 2005. Applicant has amended Claims 1 and 21, and has canceled Claims 23-43, 48-61, and 63 without prejudice. Applicant thanks Examiner Barrett for the Interview on October 18, 2005. An Interview Summary is provided below.

*Attendees, Date and Type of Interview:* The personal interview was conducted on October 18, 2005 and attended by Examiner Tom Barrett and Dr. Salima A. Merani, Esq. and Sean Kavanaugh, Esq. (counsel for Applicant).

*Exhibits and/or Demonstrations:* A prototype of one embodiment of Applicant's anulus augmentation device was shown.

*Identification of Claims Discussed:* Claim 1.

*Identification of Prior Art Discussed:* WO 97/26847 to Felt et al. and U.S. Patent No. 6,244,630 to Bao et al.

*Proposed Amendments:* Applicant will consider further defining the implant and method by adding elements directed to a frame. Applicant will amend "a fluid that is incapable of changing phase in situ" to "a fluid that remains fluid at body temperature" for clarification purposes only.

*Principal Arguments and Any Other Pertinent Matters:* Applicant argued that Claim 1 was patentable over the cited art.

*Results of Interview:* As suggested by the Examiner, Applicant agreed to consider further defining the implant by adding elements directed to a frame.

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**RCE**

Applicant has filed an RCE herewith.

***Claim Rejections<sup>1</sup>***

**Rejection under 35 U.S.C. § 112**

The Examiner rejected Claims 1-8, 11, 21-22, 44-47, and 62 under 35 U.S.C. § 112. Applicant has amended the claims to recite nuclear augmentation material comprising *a fluid that remains fluid at body temperature*.

Applicant's language complies with both the written description and enablement requirement. Applicant's specification [page 50, ¶¶ 233-4] expressly provides, inter alia:

The augmentation material 554 may remain "fluid" after the infusion step, or may polymerize, cure, or otherwise harden to a less flowable or nonflowable state.

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Additional additives and components of the nucleus augmentation material are recited below. In general, the nature of the material 554 may remain constant during the deployment and post-deployment stages or may change, from a first infusion state to a second, subsequent implanted state.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 112.

**Rejection under 35 U.S.C. § 102**

The Examiner rejected Claim 63 under 35 U.S.C. § 102(b) as being anticipated by WO 97/26847 to Felt et al. ("Felt"). **Applicant has canceled Claim 63 without prejudice.**

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<sup>1</sup> Applicant's arguments that the pending claims are patentable over the art cited herein is not an admission that the cited art qualifies as prior art. Applicant expressly reserves the right to assert that the cited art is not prior art in the future should the need arise. Moreover, Applicant reserves the right to dispute any priority dates assigned by the Examiner to Applicant's claims.

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**Rejection under 35 U.S.C. § 103(a)**

**Bao in view of Kamiya**

The Examiner rejected Claim 43 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,244,630 to Bao et al. ("Bao") in view of U.S. Patent No. 5,192,301 to Kamiya et al. ("Kamiya"). **Applicant has canceled Claim 43 without prejudice.**

**Felt in view of Ray**

The Examiner rejected Claims 1-8, 11, 21-22, 44-47, and 62 under 35 U.S.C. § 103(a) as being obvious over Felt in view of U.S. Patent No. 4,904,260 to Ray et al. ("Ray").

**The References Should Not Be Combined**

Applicant respectfully asserts that the motivation to combine Felt and Ray does not exist. For example, M.P.E.P. § 2145(X) emphasizes:

As discussed in MPEP Section 2143.01, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. The Federal Circuit has produced a number of decisions overturning obviousness rejections due to a lack of suggestion in the prior art of the desirability of combining references, as discussed in the aforementioned section.

Moreover, references that render the prior art unsatisfactory for its intended purpose cannot be combined to reject an applicant's claims.

There can be no reasonable dispute that Felt's purpose is to deliver a curable material into the disk so that it can harden and function as cartilage. Felt at page 3, lines 16-25. Felt discloses a biomaterial that must be cured (e.g., undergo a phase change) within the disc environment. Indeed, Felt narrowly defines a biomaterial as "a material that is capable of being introduced to the site of a joint by minimally invasive means, and be cured to provide desired physical-chemical properties in vivo." Felt at page 5, lines 26-29. Felt teaches that "[s]uch biomaterials are also curable, meaning that they can be cured or otherwise modified, in situ, at the tissue site, in order to undergo a phase or chemical change sufficient to retain a desired position and configuration." Felt at page 18, lines 26-28.

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In Felt, curing is **critical** because in the cured state, the biomaterial can achieve tensile strength and stiffness. Felt at page 19, lines 22-23. Moreover, an incurable liquid (e.g., a liquid that remains a liquid in the disc environment) would be inoperable using Felt's device or method. **Thus, Felt teaches away from fluids that cannot be cured or are incapable of changing phase.**

Accordingly, Felt cannot be properly combined with Ray, which discloses an aqueous solution.

Assuming arguendo that Felt can be combined with Ray (which it cannot), Applicant's claims, as amended, are patentable over that combination, as discussed below.

#### Claim Amendments

Applicant respectfully asserts that any argument that Claims 1-8, 11, 21-22, 44-47, and 62 are obvious in view of Felt alone, or in combination with other secondary references would be misplaced. Applicant has amended Independent Claim 1 and Independent Claim 21.

As amended, Claim 1 recites *a biocompatible support member, wherein said biocompatible support member comprises a metallic lattice frame and a membrane, wherein said biocompatible support member partially encapsulates the nuclear augmentation material.* The cited art does not teach or suggest these elements.

As amended, Claim 21 recites *inserting at least one annulus augmentation device to partially encapsulate the nuclear augmentation material, wherein the annulus augmentation device comprises a membrane and a frame.* Claim 21 also recites *anchoring the annulus augmentation device to the disc.* The cited art does not teach or suggest these elements.

Accordingly, Claims 1 and 21 are patentable over Felt alone, or in combination with other references. Claims 2-8, 11, 22, 44-47, and 62 are patentable because they depend from an allowable base claim and recite independently patentable features.

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New Claims 64 and 65

Applicant has added New Claims 64 and 65. No new matter has been added by these claims. New Claims 64 and 65 are patentable because they depend from an allowable base claim and because they recite an anulus augmentation device that is not inflatable or not inflated. Felt's balloon is clearly inflatable and inflated. Accordingly, Applicant respectfully asserts that New Claims 64 and 65 are patentable over the cited art.

New Claim 66

Applicant has added New Claim 66. No new matter has been added by this claims. New Claim 66 is patentable because it depends from an allowable base claim and because it recites independently patentable elements. Accordingly, Applicant respectfully asserts that New Claim 66 is patentable over the cited art.

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**CONCLUSION**

If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below. No fees are believed due. However, please charge any fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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